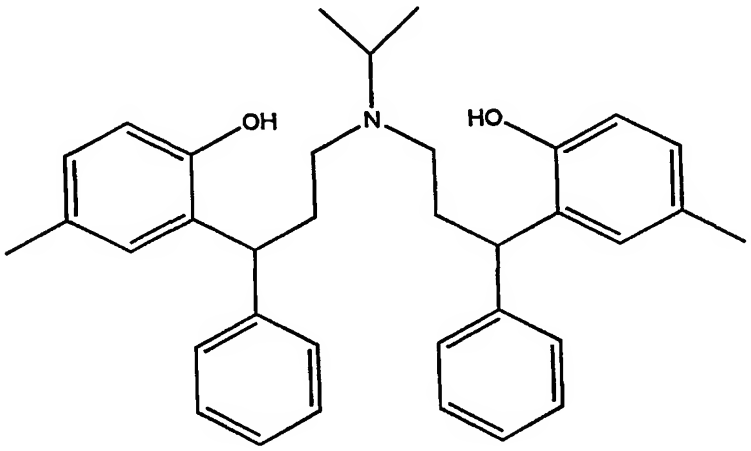
CLAIMS

1. Racemic tolterodine free base in crystalline form.

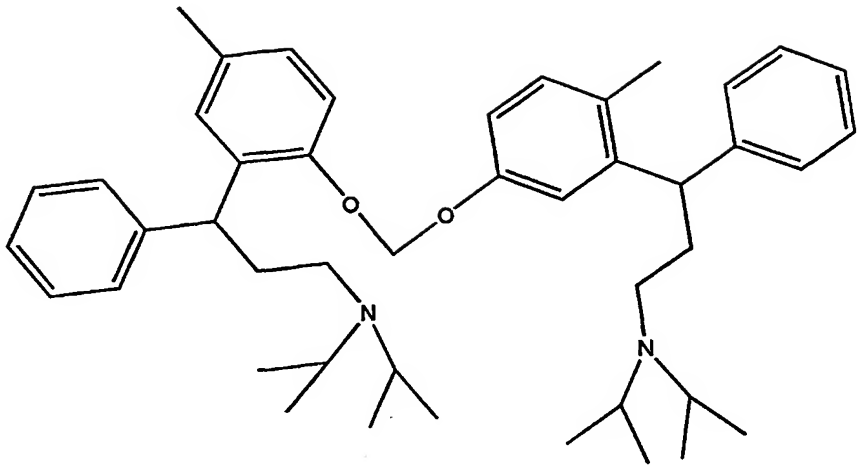
2. Racemic tolterodine free base in crystalline form containing less than about 0.2% of dimeric impurity.

3 Tolterodine according to claim 2, wherein the dimeric impurity comprises one or both of the following impurities:

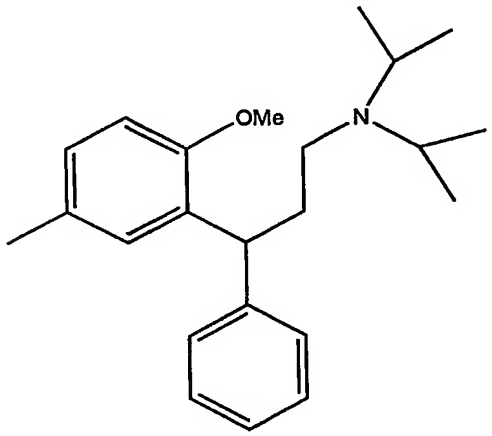
Dimer 1:



Dimer 2:



4. A process of preparing racemic tolterodine free base in crystalline form, which comprises deprotection of protected intermediate of formula (II)



(II)

wherein a solvent is present in the reaction mass obtained further to the deprotection and is selected so that a substantially mobile reaction mass is achieved at temperatures in the range of 70 to 100°C.

5. A process according to claim 4, wherein said deprotection employs pyridine hydrochloride.

6. A process according to claim 5, wherein said deprotection is carried out under an inert atmosphere at a temperature in the range of 200 to 220°C.

7. A process according to claim 6, wherein further to said deprotection said reaction mass is cooled to a temperature in the range of 110 to 130°C and said solvent is added thereto.

8. A process according to any of claims 4 to 7, wherein said solvent is dimethylformamide.

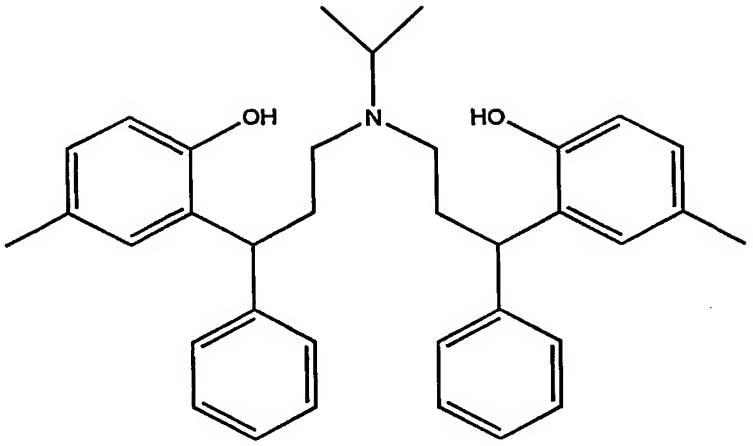
9. A process according to any of claims 4 to 8, wherein the resulting crude hydrochloride salt of racemic tolterodine is basified and the resulting racemic tolterodine free base extracted and precipitated to provide crystalline racemic tolterodine free base.

10. A process according to any of claims 4 to 9, which further comprises a purification step to obtain racemic tolterodine free base in crystalline form containing less than about 0.2% of dimeric impurity.

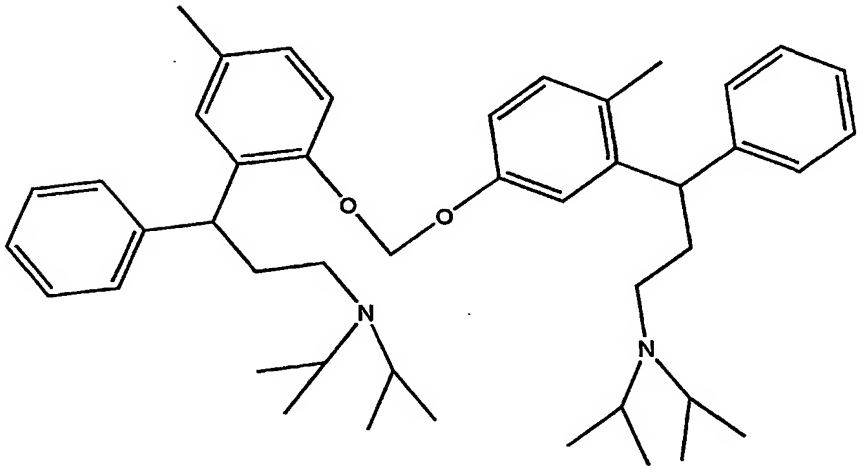
11. A process according to any of claims 4 to 10, which further comprises resolving the thus obtained racemic tolterodine free base to obtain (+)tolterodine tartrate containing less than about 0.1% of dimeric impurity.

12. A process according to claim 10 or 11, wherein said dimeric impurity comprises one or both of the following impurities:

Dimer 1:



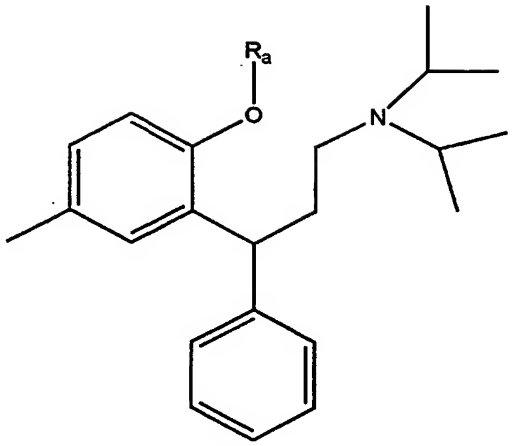
Dimer 2:



13. Racemic tolterodine free base in crystalline form prepared by a process according to any of claims 4 to 10.

14. (+)Tolterodine tartrate prepared by a process according to claim 11.

15. A process of preparing racemic tolterodine free base in crystalline form, which process comprises deprotection of a benzyl protected intermediate of formula (III)



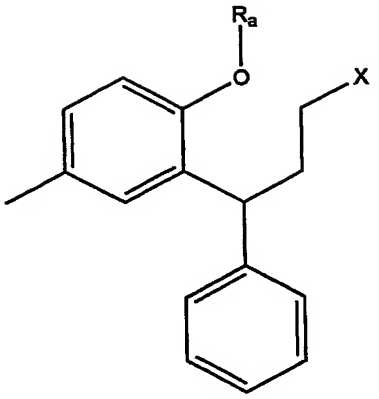
(III)

where R_a represents unsubstituted benzyl, or a substituted benzyl protecting group.

16. A process according to claim 15, which further comprise resolving the thus obtained racemic tolterodine free base to obtain (+)tolterodine tartrate containing less than about 0.1% of dimeric impurity.

17. A process according to claim 15 or 16, wherein R_a represents unsubstituted benzyl.

18. A process according to any of claims 15 to 17, wherein an intermediate compound of formula (III) is prepared by reaction of diisopropylamine with an intermediate compound of formula (IV)



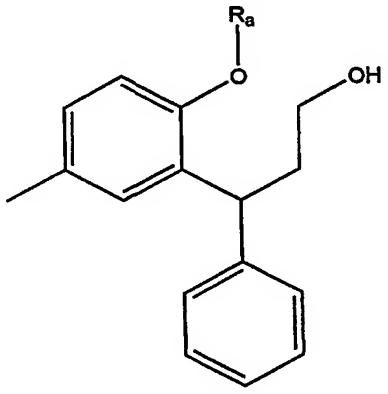
(IV)

where R_a is as defined in claim 15 and X represents a leaving group.

19. A process according to claim 18, wherein X represents arylsulphonyloxy.

20. A process according to claim 19, wherein X represents tosylate.

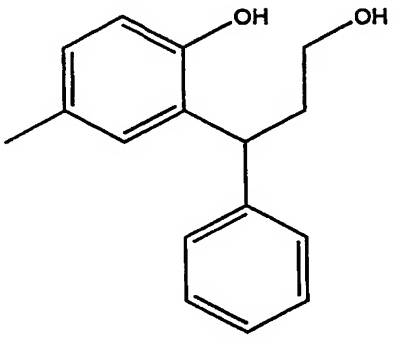
21. A process according to any of claims 18 to 20, wherein an intermediate compound of formula (IV) is prepared from an intermediate compound of formula (V)



(V)

where R_a is as defined in claim 15.

22. A process according to claim 21, wherein a compound of formula (V) is prepared by protection of an intermediate compound of formula (VI)



(VI)

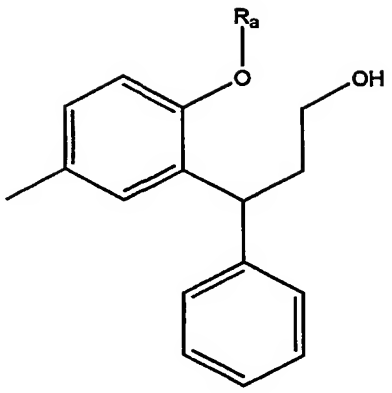
by introduction of group R_a, where R_a is as defined in claim 15.

23. A process according to claim 22, wherein a compound of formula (VI) is prepared from 6-methyl-4-phenyl-chroman-2-one.

24. Racemic tolterodine free base in crystalline form prepared by a process according to any of claims 15 or 17 to 23.

25. (+)Tolterodine tartrate prepared by a process according to claim 16.

26. An intermediate compound of formula (V)

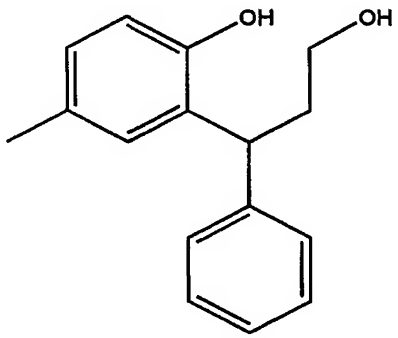


(V)

where R_a represents unsubstituted benzyl, or a substituted benzyl protecting group.

27. An intermediate of formula (V) according to claim 26, wherein R_a represents unsubstituted benzyl.

28. An intermediate compound of formula (VI)



(VI)

29. A pharmaceutical composition comprising tolterodine according to any of claims 1 to 3, 13, 14, 24 or 25, together with a pharmaceutically acceptable carrier, diluent or excipient therefor.

30. Tolterodine according to any of claims 1 to 3, 13, 14, 24 or 25, for use in therapy.

31. A method of treating a condition prevented, ameliorated or eliminated by the administration of an anti-cholinergic agent, which method comprises administration to the patient a therapeutically effective amount of tolterodine according to any of claims 1 to 3, 13, 14, 24 or 25.

32. A method according to claim 31, for the treatment of urinary incontinence.

33. Use of tolterodine according to any of claims 1 to 3, 13, 14, 24 or 25, in the manufacture of a medicament for the treatment of urinary incontinence.